

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Merck Sharp & Dohme LLC,
Petitioner,

v.

Halozyne Inc.,
Patent Owner.

Case No. PGR2025-00006
U.S. Patent No. 12,152,262

PETITIONER'S UPDATED EXHIBIT LIST

No.	Exhibit Description
1001	U.S. Patent No. 12,152,262
1002	File History of U.S. Patent No. 12,152,262
1003	Declaration of Dr. Michael Hecht
1004	Declaration of Dr. Sheldon Park
1005	U.S. Patent No. 7,767,429
1006	Chao et al., "Structure of Human Hyaluronidase-1, a Hyaluronan Hydrolyzing Enzyme Involved in Tumor Growth and Angiogenesis," <i>Biochemistry</i> , 46:6911-6920 (2007)
1007	WO 2010/077297, published 8 July 2010
1008	Stern et al., "The Hyaluronidases: Their Genomics, Structures, and Mechanisms of Action," <i>Chem. Rev.</i> 106:818-839 (2006)
1009	Jedrzejewski et al., "Structures of Vertebrate Hyaluronidases and Their Unique Enzymatic Mechanism of Hydrolysis," <i>Proteins: Structure, Function and Bioinformatics</i> , 61:227-238 (2005)
1010	Zhang et al., "Hyaluronidase Activity of Human Hyal1 Requires Active Site Acidic and Tyrosine Residues," <i>J. Biol. Chem.</i> , 284(14):9433-9442 (2009)
1011	Arming et al., "In vitro mutagenesis of PH-20 hyaluronidase from human sperm," <i>Eur. J. Biochem.</i> , 247:810-814 (1997)
1012	Bordoli et al., "Protein structure homology modeling using SWISS-MODEL workspace," <i>Nature Protocols</i> , 4(1):1-13 (2008)
1013	Frost, "Recombinant human hyaluronidase (rHuPH20): an enabling platform for subcutaneous drug and fluid administration," <i>Expert Opinion on Drug Delivery</i> , 4(4):427-440 (2007)
1014	Brandon & Tooze, "Introduction to Protein Structure," Second Ed., Chapters 1-6, 11-12, 17-18 (1999)
1015	Table Associating Citations from the '262 Patent (EX1001) to Corresponding Citations in the '731 Application (EX1026)
1016	Steipe, "Consensus-Based Engineering of Protein Stability: From Intrabodies to Thermostable Enzymes," <i>Methods in Enzymology</i> , 388:176-186 (2004)

No.	Exhibit Description
1017	Green, “Computer Graphics, Homology Modeling, and Bioinformatics,” Protein Eng’g & Design, Ch. 10, 223-237 (2010)
1018	Chica et al., “Semi-rational approaches to engineering enzyme activity: combining the benefits of directed evolution and rational design,” Curr. Opin. Biotechnol., (4):378-384 (2005)
1019	Hardy et al., “Assessment of contraceptive vaccines based on recombinant mouse sperm protein PH20,” Reprod., 127:325-334 (2004)
1020	Pomering et al., “Restricted Entry of IgG into Male and Female Rabbit Reproductive Ducts Following Immunization with Recombinant Rabbit PH-20,” Am. J. Reprod. Immunol., (3):174-82 (2002)
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1022	Primakoff et al., “Reversible Contraceptive Effect of PH-20 Immunization in Male Guinea Pigs,” Biol Reprod., 56(5):1142-6 (1997)
1023	Tung et al., “Mechanism of Infertility in Male Guinea Pigs Immunized with Sperm PH-20,” Biol. Reprod., 56(5):1133-41 (1997)
1024	Rosengren et al., “Recombinant Human PH20: Baseline Analysis of the Reactive Antibody Prevalence in the General Population Using Healthy Subjects,” BioDrugs, 32(1):83-89 (2018)
1025	U.S. Patent No. 9,447,401
1026	U.S. Patent Application No. 13/694,731
1027	2024 Chemistry Nobel Prize Background
1028	[Reserved]
1029	Gmachl et al., “The human sperm protein PH-20 has hyaluronidase activity,” FEBS Letters, 3:545-548 (1993)
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1045	Redline Comparison of the '731 and '262 Specifications
1046	Beasley & Hecht, "Protein Design: The Choice of de Novo Sequences," J. Biological Chemistry, 272:2031-2034 (1997)
1047	Xiong et al., "Periodicity of Polar and Nonpolar Amino Acids is the Major Determinant of Secondary Structure in Self-Assembling Oligomeric Peptides," PNAS, 92: 6349-6353 (1995)
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1050	Pace & Scholtz, "A Helix Propensity Scale Based on Experimental Studies of Peptides and Proteins," Biophysical J. 75:422-427 (1998)
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1062-1063	[Reserved]

No.	Exhibit Description
1064	Collection of BLAST Webpages from the Internet Archive, navigable from: https://web.archive.org/web/20111022151531/http://www.clustal.org/omega/
1065	Collection of Clustal Omega Webpages from the Internet Archive, navigable from: https://web.archive.org/web/20111022151531/http://www.clustal.org/omega/
1066	Collection of SWISS-MODEL Webpages from the Internet Archive, navigable from: https://web.archive.org/web/20110519141121/http://swissmodel.expasy.org/?pid=smh01&uid=&token=
1067	Collection of PyMol Webpages from the Internet Archive, navigable from: https://web.archive.org/web/20110701072314/http://pymol.org/
1068	Declaration of Jeffrey P. Kushan
1069	Swiss Model Printout of PH20 Model
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1073	Swiss Model Printout of PH20 Model with L317S Mutation
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1075	Declaration of Leif E. Peterson, II
1076-1081	[Reserved]
1082	United States District Court – National Judicial Caseload Profile, navigable from: https://www.uscourts.gov/data-news/reports/statistical-reports/federal-court-management-statistics/federal-court-management-statistics-december-2024
1083	Table Showing Outcomes of Disputed Motions to Stay Pending IPRs in DNJ

No.	Exhibit Description
1084	News Release: “Halozyme Raises 2025 Financial Guidance Ranges and Reports Strong First Quarter 2025 Results,” navigable from: https://www.prnewswire.com/news-releases/halozyme-raises-2025-financial-guidance-ranges-and-reports-strong-first-quarter-2025-results-302447541.html
1085	News Release: “Merck Breaks Ground on New \$1 Billion Biologics Center of Excellence in Wilmington, Delaware,” navigable from: https://www.merck.com/news/merck-breaks-ground-on-new-1-billion-biologics-center-of-excellence-in-wilmington-delaware/
1086	Halozyme Therapeutics, Inc. Q1 2025 Earnings Call Transcript (May 6, 2025)
1087-1112	[Reserved]
1113	Declaration of Sue Wang
1114	Declaration of Brian M. Goldberg
1115	Declaration of Katherine A. Helm
1116-1118	[Reserved]
1119	Csoka, A. et al., “The Six Hyaluronidase-Like Genes in the Human and Mouse Genomes” Matrix Biology 20:499-508 (2001)
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1123-1124	[Reserved]
1125	Emails re: AutoDock Vina (Sept. 9, 2025 - Oct. 27, 2025)

No.	Exhibit Description
1126	Im, S. et al., “Cryo-EM Structure of Human Hyaluronidase PH-20,” <i>Proteins: Structure, Function, and Bioinformatics</i> 93:1067-1073 (2025)
1127-1128	[Reserved]
1129	Transcript of the Deposition of Dr. Gary Cherr, Ph.D., November 12, 2025
1130	Melanie Ann Simpson, Ph.D. Deposition Transcript
1131	Gregory Petsko, Ph.D. Deposition Transcript
1132	Transcript of the Deposition of Dr. James Moon, Ph.D., November 18, 2025
1133	Declaration of James Naismith, Ph.D.
1134	Declaration of Dr. Garnett Kelsoe
1135	Dr. Naismith Analysis Spreadsheet
1136	Dobson, “Principles of protein folding, misfolding and aggregation” <i>Semin. Cell. Dev. Biol.</i> 15(1):3-16 (2004)
1137	Dobson, “Protein folding and misfolding” <i>Nature</i> . 18;426(6968):884-90 (2003)
1138	Dobson, “Experimental investigation of protein folding and misfolding” <i>Methods</i> 34(1):4-14 (2004)
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1141	Goldsmith & Tawfik, “Directed enzyme evolution: beyond the low-hanging fruit” <i>Curr. Opin. Struct. Biol.</i> 22(4):406-12 (2012)
1142	Farber & Petsko, “The evolution of alpha/beta barrel enzymes” <i>Trends Biochem. Sci.</i> 15(6):228-34 (1990)
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1154	Second Table Associating Citations from the '262 Patent (EX1001) to Corresponding Citations in the '731 Application (EX1026)
1155	Calloni et al., “Investigating the Effects of Mutations on Protein Aggregation in the Cell” J. Biol. Chem. 10607-13 (2005)

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1156	Chiti et al., “Studies of aggregation of mutant proteins in vitro provided insights into genetics of amyloid diseases” PNAS 99:16419-26 (2002)
1157	Chiti et al., “Rationalization of the effects of mutations on peptide and protein aggregation rates” Nature, 424:805-808 (2003)
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1161	Primakoff, P. et al., “Purification of the guinea pig sperm PH-20 antigen and detection of a site-specific endoproteolytic activity in sperm preparations that cleaves PH-20 into two disulfide-linked fragments,” Biology of Reproduction 38:921-934 (1988)
1162	Koch, C. et al., “A Comparison of the Immunogenicity of the Native and Denatured Forms of a Protein,” APMIS 104:115-125 (1996)
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1166	MERCK_PGR00462 - RE_2_25-cv-03179-ES-JRA_HALOZYME, INC. v. MERCK SHARP & DOHME CORP.
1167	MERCK_PGR00094 - DNJ-2-25-cv-03179 Stipulation to Substitute Parties
1168	MERCK_PGR00090 - DNJ-2-25-cv-03179 2025-07-14 [019] Corporate Disclosure Statement

No.	Exhibit Description
1169	Declaration of Jeffrey P. Kushan (Petitioner's Reply)
1170	Murphy, K., “Janeway’s Immuno Biology,” (8th 2012), Chapters 1, 4, 8, 10, 11, 12, 15, and Appx I
1171	Yang, X. et al., “An Introduction to Epitope Prediction Methods and Software,” Rev. Med. Virol., 19: 77–96 (2009)
1172	Bolland, S., “An Innate Path to Human B Cell Tolerance,” Immunity, 29(5):667-9 (2008)
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1182	Levine, B. and Levytska, V., “A Sensitive Hemagglutination Assay Method for Dinitrophenyl-Specific Antibodies. The Effect of Antibody Binding Affinity on Titers,” J Immunol., 98(3):648-52 (1967)
1183	Fauci, A. et al., “The Relationship between Antibody Affinity and the Efficiency of Complement Fixation,” J Immunol., 105(1):215-20 (1970)
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1189	Martin-Deleon, “Epididymal SPAM1 and its Impact on Sperm Function” Molecular and Cellular Endocrinology 250:114-121 (2006)
1190	Nolan et al., “The Safety of Recombinant Human Hyaluronidase PH20 in Nonclinical Models: An Overview of Toxicology, Pharmacology, and Impact of Anti-PH20 Antibodies,” Journal of Controlled Release, 374:369-383 (2024)
1191	McCutcheon, J. et al., “HLA-B*0702 Antibody Epitopes are Affected Indirectly by Distant Antigen Residues,” Hum Immunol., 36(2):69-75 (1993)

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1192	Nobusawa, E. et al., “Comparison of Complete Amino Acid Sequences and Receptor-Binding Properties among 13 Serotypes of Hemagglutinins of Influenza A Viruses,” <i>Virology</i> , 182(2):475-85 (1991)
1193	CDC on H5N1 CDC Press Release: “Highly Pathogenic Avian Influenza A (H5N1) Virus Infection Reported in a Person in the U.S.” (Apr. 1, 2024)
1194	[Reserved]
1195	Zhang, H. et al., “Mouse Spam1 (PH-20) Is a Multifunctional Protein: Evidence for Its Expression in the Female Reproductive Tract,” <i>Biol Reprod.</i> , 69(2):446-54 (2003)
1196	Dunn, C. et al., “Transcription of the Human and Rodent SPAM1 / PH-20 Genes Initiates Within an Ancient Endogenous Retrovirus,” <i>BMC Genomics</i> , 6:47 (2005)
1197	Hirsch, C. et al., “The Ubiquitylation Machinery of the Endoplasmic Reticulum,” <i>Nature</i> , 458(7237):453-60 (2009)
1198	Singh, S., et al., “Solubilization and Refolding of Bacterial Inclusion Body Proteins,” <i>Journal of Bioscience and Bioengineering</i> 99:303-310 (2005)
1199	Li, M. et al., “Importance of Glycosylation and Disulfide Bonds in Hyaluronidase Activity of Macaque Sperm Surface PH-20,” <i>J Androl.</i> , 23(2):211-9 (2002)
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1201	Rodriguez, L. et al., “Foot and mouth disease virus vaccines,” <i>Vaccine</i> 27:D90-D94 (2009)
1202	Redwood, A. et al., “Viral Vectored Immunocontraception: Screening of Multiple Fertility Antigens using Murine Cytomegalovirus as a Vaccine Vector,” <i>Vaccine</i> , 25(4):698-708 (2007)
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1204	Nikolova E. et al., “All Forms of Human IgA Antibodies Bound to Antigen Interfere with Complement (C3) Fixation Induced by IgG or by Antigen Alone,” Scand J Immunol., 39(3):275-80 (1994)
1205	Goodey, N. et al., “Allosteric Regulation and Catalysis Emerge via a Common Route,” Nat Chem Biol. 4(8):474-82 (2008)
1206-1223	[Reserved]
1224 [NEW]	Declaration of Kelly Grez – Protective Order Material
1225-1233	[Reserved]
1234	MSD Netherlands Capital B.V., Preliminary Prospectus Supplement (May 14, 2024)
1235	Merck & Co., Inc., Form 8-K (Nov. 4, 2009)
1236	Jennifer_Zachary WD_Redacted – Protective Order Material
1237	Merck & Co., Inc. Subsidiaries (Dec. 31, 2024)
1238	State of New Jersey, Certificate of Long Form Standing with Officers and Directors, Merck & Co., Inc. (Feb. 18, 2026)
1239	Press Release: “Merck and Schering-Plough to Merge” (Mar. 9, 2009)
1240	State of New Jersey, Certificate of Long Form Standing with Officers and Directors, Merck Sharp & Dohme LLC (Feb. 18, 2026)
1241	Company Statement: “Merck Sues Merck KGaA, Darmstadt, Germany for Improper Use of “Merck”” (Jan. 15, 2016)
1242	ZacharyJennifer ADP_Redacted – Protective Order Material
1243	Table Comparing the Boards of Directors for Merck & Co., Inc. and Merck Sharp & Dohme LLC

No.	Exhibit Description
1244	Merck & Co., Inc., Form 851 – Affiliations Schedule for Tax Year Ending Dec. 31, 2024

Dated: March 12, 2026

Respectfully Submitted,

/Jeffrey P. Kushan/

Jeffrey P. Kushan
Reg. No. 43,401
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005
jkushan@sidley.com
(202) 736-8914
Attorney for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I hereby certify that on this 12th day of March, 2026, I caused to be served a true and correct copy of the foregoing and any accompanying exhibits by e-mail on the following counsel of record for Patent Owner:

Eldora L. Ellison, eellison-PTAB@sternekessler.com
R. Wilson Powers III, tpowers-PTAB@sternekessler.com
Jennifer Meyer Chagnon, jchagnon-PTAB@sternekessler.com
David H. Holman, dholman-PTAB@sternekessler.com
Tyler C. Liu, tliu-PTAB@sternekessler.com
David J. Kappos, dkappos@cravath.com
Aubrey Haddach, ahaddach@halozyme.com
Louis P. Panzica, Jr., lpantzica-PTAB@sternekessler.com
Joshua A. Mack, jmack@halozyme.com
Lauren N. Martin, laurenmartin@quinnemanuel.com
Mark H. Snyder, msnyder@halozyme.com
Pratibha Khanduri, pkhanduri-PTAB@sternekessler.com
Zachariah Summers, zachsummers@quinnemanuel.com
PTAB@sternekessler.com

Dated: March 12, 2026

Respectfully Submitted,

/Jeffrey P. Kushan/

Jeffrey P. Kushan
Reg. No. 43,401
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005
jkushan@sidley.com
(202) 736-8914
Attorney for Petitioner